

practice of the invention in this country of a NAFTA or WTO member country prior to the effective date of Crutchfield. Examiner Rines stated that Applicant's declaration consists of a "Letter Of Agreement" between HealthHelp, Inc. and Tri-Med Management, Inc. The letter includes a general working arrangement between the two parties with regard to a joint interest designated as the Beverly Nursing Homes. The letter fails to include substantive evidence of the existence of the claimed invention directed to "classification and management system for patients with lower extremity arterial occlusive disease..." at the time of the "Letter Of Agreement".

In response to the § 101 rejection, Claim 17 is a classification and management system for patients with lower extremity arterial occlusive disease that includes examining, evaluating, classifying, assessing, monitoring and treating the disease. The method includes the steps of collecting patient data including noninvasive arterial pressure and blood flow data, comparing the collected patient data against a medically accepted set of disease specific criteria, evaluating those "potentially at risk" patients against medically accepted criteria, classifying each patient against medically accepted criteria as "at risk" or "not at risk" of developing arterial occlusive disease, assessing such "at risk" patients against medically accepted criteria as "clinical indication for operation" or "no indication for operation", reassessing the referred patient against medically accepted criteria as "no indication for operation" or "clinical indication for operation".

The value of the noninvasive pressure measurements used in the claimed process is that subjectivity is eliminated from the equation. In the past, prior to

Applicant's invention a clinician would examine a patient and conclude that the patient does or does not have a significant problem with limb arterial perfusion. Another clinician might examine the same patient and reach a different conclusion. Current noninvasive techniques for arterial pressure and flow measurements were a major advance because these objective standards removed subjectivity from the equation.

The criteria for diagnosing inadequate blood flow are specifically defined both in Applicant's program and in the medical literature established years ago. In the few patients in which ankle vessel wall calcification precludes accurate measurement of arterial pressure, toe pressure and/or ankle Doppler wave form analysis both provide objective results which can establish the diagnosis.

This criteria and application to patients with lower extremity arterial occlusive disease are found in the literature. For example:

- Vascular Surgery Principles and Practice Textbook with Wilson, Veith, Hobson and Williams as editors. The most pertinent information is contained on pages 86 – 89.
- Vascular Surgery (3rd Ed.) Rutherford ed. The most pertinent information is contained on pages 61 – 68, 70 – 79 and 86 - 92.

In addition, articles discussing tests that provide medically accepted criteria based upon objective results are found in:

Wound Healing Perspectives, Volume 3 No. 2 Spring 2006,

The Memorial Hermann Center For Wound Healing

Critical Limb Ischemia By Alain Branchereaux, Michael Jacobs.

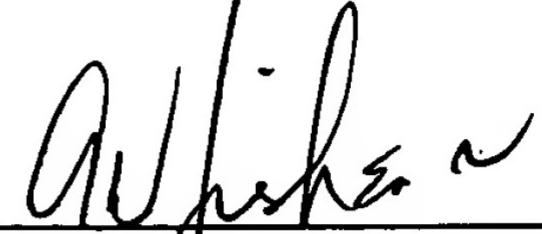
Applying these objective test results in Applicant's method yields reliable, respectable medically acceptable diagnosis and treatment. Accordingly, Applicant respectfully requests Examiner Rines reconsider the § 101 rejection.

Regarding the § 101 rejection, Crutchfield simply discloses a method for assessing vascular health including assessing blood flow in blood vessels, for assessing vascular health, for conducting clinical trials, for screening therapeutic interventions for adverse effects, and for assessing the effects of risk factors, therapies and substances, including therapeutic substances, on blood vessels, especially cerebral blood vessels, all achieved by measuring various parameters of blood flow in one or more vessels and analyzing the results in a defined manner. The relevant parameters of blood flow include mean flow velocity, systolic acceleration, and pulsatility index. By measuring and analyzing these parameters, one can ascertain the vascular health of a particular vessel, multiple vessels and an individual. Such measurements can also determine whether a substance has an effect, either deleterious or advantageous, on vascular health. Crutchfield is directed to the observation and measurement of specific vascular indicators and in no way teaches, suggests or motivates one to the method of treatment of lower extremity arterial occlusive disease as claimed in the instant application. Moreover, Applicant earlier submitted a Declaration swearing behind Crutchfield setting forth in exhaustive detail the invention claimed in the instant application predating Crutchfield. A copy of the Declaration is attached.

Accordingly, Applicant respectfully requests Examiner Rines reconsider the § 103 rejection.

If any matters remain outstanding, Applicant's attorney invites Examiner Rines to contact him by telephone.

Respectfully submitted,



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